UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE

IN RE: VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION	MDL No. 2875 Honorable Robert B. Kugler, District Court Judge
This Document Relates to All Actions	**Oral Argument Requested**

DEFENDANTS' MEMORANDUM OF LAW IN OPPOSITION TO PLAINTIFFS' *DAUBERT* MOTION TO PRECLUDE OPINIONS OF DEFENSE EXPERT TIMOTHY E. KOSTY

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RULE

Plaintiffs' motion rests on the false premise that because this Court excluded ***some*** of the opinions offered by Timothy Kosty at the class certification stage, ***all*** of the opinions in his current report are necessarily inadmissible. In fact, many of Mr. Kosty's current opinions have previously been deemed admissible by the Court – and those that have not previously been addressed fall within Mr. Kosty's expertise and are based on a reliable methodology. Accordingly, plaintiffs' motion should be denied.[1]

FACTUAL BACKGROUND

Mr. Kosty's first report addressed issues related to plaintiffs' motion for class certification, including responses to certain expert opinions offered by Dr. Rena Conti, Laura Craft and Dr. Kaliopi Panagos in support of plaintiffs' motion for class certification. (*See* Report of Timothy E. Kosty ("Kosty Class Rep."), Jan. 12, 2022 (Pls.' Br. Ex. 2).) Mr. Kosty's current report (Report of Timothy E. Kosty ("Kosty Rep."), Dec. 19, 2022 (Pls.' Br. Ex. 1)) responds to plaintiffs' subsequent and separate expert reports, including Ms. Craft's and Dr. Panagos's new reports addressing "liability" issues related to claims alleged by MSP Recovery Claims Services, LLC as an assignee on behalf of two third-party payors ("TPPs"),

[1] To the extent the Court determines that any opinions set forth in Mr. Kosty's December 19, 2022 report are covered by, and inadmissible under, the Court's order on class certification experts (*see* ECF No. 2261), defendants incorporate their prior briefing (*see* ECF No. 2077) and preserve their objections for appeal.

SummaCare, Inc. ("SummaCare") and EmblemHealth ("Emblem"), that had been set for trial prior to the Court's certification order. (*See* Declaration of Laura R. Craft, MPH, Oct. 31, 2022 (ECF No. 2287-3); Report of Kali Panagos, Pharm.D., RPH, Oct. 31, 2022 (ECF No. 2294-2).) Although there are overlapping subjects, Mr. Kosty's latest report adjusts, expands upon, and adds to the opinions set forth in the Kosty Class Report. Mr. Kosty also thoroughly explained the methodologies he employed in formulating his new criticisms of Ms. Craft and Dr. Panagos. (*See* Dep. of Timothy E. Kosty ("Kosty Dep.") 136:4-140:12, 150:4-152:22, Feb. 23, 2023 (attached as Ex. 1 to the Certification of Jessica Davidson).)

The Court issued its ruling with respect to both plaintiffs' motion for class certification and the parties' various motions to exclude class certification experts on February 8, 2023, after submission of both parties' "liability" expert reports. (*See* ECF No. 2261.) The Court granted in part and denied in part plaintiffs' motion to exclude Mr. Kosty's class certification opinions. As an initial matter, the Court held that "Mr. Kosty's qualifications based on his 38 years of experience in the pharmacy business, mainly as a consultant to the pharmaceutical industry, support his exposition at pp. 15-48 of his Report of the workings of the pharmaceutical industry" and that these opinions "fit, i.e., [are] relevant, to" class certification "as well as to general considerations of loss experienced by the Economic Loss classes." (*Id.* at 79.) The Court, however, granted plaintiffs' motion with respect to specific portions

of the Kosty Class Report responding to "three of plaintiffs' class certification experts' reports: Laura Craft's Report on an acceptable methodology for identifying proposed economic class members and on the amount paid for the VCDs; Dr. Rena Conti's Report on valuation of economic losses by consumers and TPPs; and Dr. Kaliopi Panagos's Report on the use of the Orange Book by the drug industry." (*Id.*)

ARGUMENT

Rule 702 provides that expert testimony is admissible if the witness is qualified and the opinion is "based on sufficient facts or data" and "the product of reliable principles and methods" that have been "reliably applied . . . to the facts of the case." Fed. R. Evid. 702. As set forth below, Mr. Kosty's opinions satisfy these standards.

I. THE COURT HAS HELD THAT MR. KOSTY'S OPINIONS REGARDING THE STRUCTURE AND EFFECT OF MEDICARE PART D ARE ADMISSIBLE.

Plaintiffs' motion ignores the Court's previous holding that Mr. Kosty's opinions related to "the workings of the U.S. pharmaceutical industry" are admissible under Rule 702. (ECF No. 2261 at 3, 80 (admitting opinions included in pages 15-48 of the Kosty Class Report).) The portion of the Kosty Class Report deemed admissible by the Court included an explanation of federal subsidies to TPPs under Medicare Part D – and the effect those subsides would have on TPP

expenditures in connection with paying for prescription medications. (*See, e.g.*, Kosty Class Rep. at 29-31, 42, 45-48.)

Mr. Kosty offers similar opinions in his current report. Specifically, he explains the "structure of Medicare Part D plans," including those offered by SummaCare and Emblem; describes "the flow of funds for prescriptions covered under Medicare Part D"; and opines that, as a result of Medicare Part D, prescription drug costs "are borne almost entirely, if not exclusively, by the[TPPs'] enrollees and the federal government." (Kosty Rep. ¶¶ 26-37 (capitalization altered).) The Court has already recognized that Mr. Kosty's "38 years of experience in the pharmacy business" (ECF No. 2261 at 79), which included work with Medicare Part D plans (Kosty Rep. ¶ 5), provides him a reliable basis to offer these opinions, and that they are "relevant" to the "general considerations of loss experienced by" TPPs such as SummaCare and Emblem. (ECF No. 2261 at 79.) Accordingly, the Court should once again reject plaintiffs' efforts to exclude these opinions.

II. A NUMBER OF MR. KOSTY'S CRITICISMS OF PLAINTIFFS' EXPERTS ARE ADMISSIBLE UNDER THE COURT'S PRIOR ORDER.

Although the Court previously excluded Mr. Kosty's specific responses to certain class certification opinions offered by Ms. Craft and Dr. Panagos, the Court has not addressed most of the rebuttal opinions offered in his new report, which are admissible as a matter of law here.

First, the Court has not addressed Mr. Kosty's opinion that Ms. Craft's economic loss opinions fail to take account of Medicare Part D reimbursements.

Mr. Kosty's previous report criticized Ms. Craft's opinion that there is an administratively feasible mechanism for identifying members of the proposed economic loss class for purposes of class certification. (*See* Kosty Class Rep. at 49-81.) The Court excluded these class-certification-related opinions on grounds that: (1) Mr. Kosty sought to "take the place of this Court as arbiter of whether the ascertainability requirement of Rule 23(b)(3) has been met"; and (2) his opinion that ascertaining class membership would require "complex data tracking of individual class members" was not "legally sufficient to nullify ascertainability." (ECF No. 2261 at 79-80.) But Mr. Kosty's current report does not include these criticisms, which relate to class certification alone. Instead, Mr. Kosty builds upon his explanation of the effect of Medicare Part D subsidies, addressed above, and opines that Ms. Craft's evaluation of the TPPs' economic losses should have accounted for them. (*See* Kosty Rep. ¶¶ 43-46.)

Plaintiffs argue that Mr. Kosty's opinions about the need to account for Medicare Part D subsidies are inadmissible because Mr. Kosty criticized Dr. Conti's theory of damages for the same reason at the class-certification stage and those opinions were excluded. (*See* Pls.' Br. at 9.) But the Court precluded Mr. Kosty from criticizing "Dr. Conti's proposition that the recalled [valsartan containing drugs

("VCDs")] were economically ***worthless***" based on a finding that he is not qualified to "value[e] either the market forces of drug sales or supply chain flow" and did not cite sufficient "literature or consumer market research" to support his position. (ECF No. 2261 at 80 (emphasis added).) In his current report, Mr. Kosty does not opine on the "value" of the VCDs at issue or whether they were worthless. Rather, he opines that the "nature of Medicare Part D plans" is relevant to what (if any) costs were borne by TPPs like MSP's assignors, SummaCare and Emblem. (*See* Kosty Rep. ¶¶ 43-46.) As noted above, these opinions are the product of Mr. Kosty's relevant expertise and are sufficiently supported.

There is also no merit to plaintiffs' argument that Mr. Kosty's criticisms of Ms. Craft are inadmissible because he "does not attempt to undertake any analysis of how much any monies from Medicare 'offset' the TPPs' economic losses." (Pls.' Br. at 10-11.) Indeed, this assertion is contrary to ample caselaw making clear that "[i]t is the proper role of rebuttal experts to critique plaintiffs' expert[s'] methodologies and point out potential flaws in the plaintiffs' experts' reports" and therefore they need not "produce models or methods of their own." *Winn-Dixie Stores, Inc. v. E. Mushroom Mktg. Coop.*, No. 15-6480, 2021 WL 2352016, at *14 (E.D. Pa. June 9, 2021) (citation omitted); *see also Holbrook v. Lykes Bros. S.S. Co.*, 80 F.3d 777, 786 (3d Cir. 1996) (explaining that "the test is different" for rebuttal experts offered to "help the jury to evaluate testimony by plaintiff[s'] expert[] . . .

[on] an issue on which plaintiff[s bear] the burden of proof"); *In re Zyprexa Prods. Liab. Litig.*, 489 F. Supp. 2d 230, 285 (E.D.N.Y. 2007) ("[D]efendants' experts have a less demanding task, since they have no burden to produce models or methods of their own; they need only attack those of plaintiffs' experts."); *APEX Fin. Options, LLC v. Gilbertson*, No. 19-0046-WCB-SRF, 2022 WL 613347, at *3 (D. Del. Mar. 1, 2022) (explaining that "as a rebuttal witness it was enough for [an expert] to critique [the opposing party's expert's] analysis; it was not necessary for him to offer an alternative approach"); *In re Abilify (Aripiprazole) Prods. Liab. Litig.*, 299 F. Supp. 3d 1291, 1368 (N.D. Fla. 2018) (it was "entirely appropriate" for defendants' experts to offer "essentially, critiques of [p]laintiffs' experts' evidence, methodologies, and conclusions").[2]

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[2] *See also, e.g.*, *Autotech Techs., LP v. Palmer Drives Controls & Sys., Inc.*, No. 19-cv-00718-PAB-NRN, 2023 U.S. Dist. LEXIS 30372, at *26 (D. Colo. Feb. 23, 2023) ("[A] rebuttal expert is not required to independently calculate a plaintiff's lost profits; a rebuttal expert 'must restrict their testimony to attacking the theories offered by the adversary's experts.'") (citation omitted); *HP Tuners, LLC v. Cannata*, No. 3:18-cv-00527-LRH-CSD, 2023 U.S. Dist. LEXIS 14593, at *14 (D. Nev. Jan. 27, 2023) ("[W]hile [plaintiff] questions whether [defense rebuttal expert] offers any independent opinions or calculations, failure to do so would not provide sufficient grounds for exclusion."); *IceMOS Tech. Corp. v. Omron Corp.*, No. CV-17-02575-PHX-JAT, 2019 WL 4750129, at *10 n.9 (D. Ariz. Sept. 30, 2019) ("As a rebuttal witness, [expert] can rely on [opposing expert's] report to point out flaws in [his] analysis or conclusion" and "need not conduct an 'independent analysis.'"); *In re Cessna 208 Series Aircraft Prods. Liab. Litig.*, MDL No. 1721, 2009 U.S. Dist. LEXIS 63185, at *16 (D. Kan. June 9, 2009) (a "rebuttal expert who critiques another expert's theories or conclusions need not offer his own independent theories or conclusions").

Mr. Kosty does not seek to offer an affirmative opinion regarding the amount of the TPPs' purported losses; instead, he explains that Ms. Craft's opinions are inconsistent with the reality of how Medicare Part D works. It would be erroneous to exclude such rebuttal opinions, which will help the jury "properly weigh the testimony" of Ms. Craft. *United States v. Velasquez*, 64 F.3d 844, 848, 851 (3d Cir. 1995).

Second, contrary to plaintiffs' assertion, the Court did not previously bar Mr. Kosty from offering ***any*** opinions regarding the role the FDA's Orange Book plays in TPP coverage decisions. (Pls.' Br. at 12-14.) Instead, the Court held that Mr. Kosty did not have sufficient support for his assertion – offered in response to Dr. Panagos's opinion "that the FDA's Orange Book acts as a warranty to consumers and their insurers" – that "the drug industry would not have regarded the Orange Book as a warranty." (ECF No. 2261 at 80.) According to the Court, such opinions about "the drug industry's 'perceptions' needed more reliable support than [Mr. Kosty's] mere disagreement." (*Id*.) But the Court also went on to ***exclude Dr. Panagos's opinions that the Orange Book constitutes a warranty*** because this "is a legal question to be posed to, and answered by, the factfinder after a review of relevant facts." (*Id.* at 94.) As explained in detail in defendants' pending motion to exclude Dr. Panagos, her current report includes substantively identical opinions that the Orange Book serves as an "assurance" to the pharmaceutical industry that should

be excluded for the same reason. (ECF No. 2294 at 27-33 (citing testimony by Dr. Panagos that "assurance or warranty, they really mean the same thing").) If these opinions are properly excluded, Mr. Kosty would have no need to rebut them.

Mr. Kosty is, however, entitled to offer the other opinions regarding the Orange Book included in his current report, including his explanation of how the pharmaceutical industry, and P&T committees in particular, use it. (Kosty Rep. ¶¶ 49-64.) Such opinions fall within the scope of this Court's prior order finding that Mr. Kosty is qualified to "explain . . . practices in the U.S. drug industry." (ECF No. 2261 at 79.) The same is true of Mr. Kosty's opinions that Dr. Panagos "mischaracterize[s] . . . other aspects of standard industry practice regarding information provided for drugs and Medicare Part D financing," including "the structure and funding of Medicare Part D plans," the "use of Medication Guides," and the requirements for prescription drug "Package Inserts." (Kosty Rep. ¶¶ 65-68.) All of these opinions relate directly to the "workings of the pharmaceutical industry," which the Court has already held Mr. Kosty can address based on his "38 years of experience in the pharmacy business." (ECF No. 2261 at 79.) In addition, Mr. Kosty has addressed this Court's prior criticism that he did not fully explain his methodology. As Mr. Kosty has made clear, his current criticisms of both Ms. Craft and Dr. Panagos are based on the same issue-assessment methodology he uses in his day-to-day consulting practice, including both review of the source documents and

evaluation of industry payor segments; are the product of his 40 years of industry experience; and are supported by cited literature on which he relied in forming his opinions. (*See* Kosty Dep. 136:4-140:12.)

CONCLUSION

For the foregoing reasons, and those set forth in defendants' prior briefing, plaintiffs' motion to preclude the opinions of Mr. Timothy Kosty should be denied.

Dated: April 11, 2023

Respectfully submitted,

By: */s/ Jessica Davidson*

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on April 11, 2023, I electronically filed the foregoing with the Clerk of the Court by using the CM/ECF system, which will send a notice of electronic filing to all CM/ECF participants in this matter.

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